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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,091	12/16/2004	Giancarlo Cravotto	48239	5511
1609	7590	08/10/2006	EXAMINER	
ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.			CARR, DEBORAH D	
1300 19TH STREET, N.W.				
SUITE 600			ART UNIT	PAPER NUMBER
WASHINGTON,, DC 20036			1621	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/518,091	CRAVOTTO, GIANCARLO	
	Examiner	Art Unit	
	Deborah D. Carr	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 8-9, filed 15 May 2006, with respect to claims 1-12 & 20 have been fully considered and are persuasive. The rejection of claims 1-12 & 20 under 35 USC §112 1st paragraph enablement regarding making has been withdrawn.
2. Applicant's arguments see page 9-10, filed 15 May 2006, with respect to claims 1-12, 16-18 & 20 have been fully considered and are persuasive. The rejection of claims 1-12, 16-18 & 20 under 35 USC §112 2nd paragraph has been withdrawn.
3. Applicant's arguments, see page 10-11, filed 15 May 2006, with respect to claims 1 & 8 have been fully considered and are persuasive. The rejection of claims 1 & 8 under 35 USC 102(b) has been withdrawn.
4. Applicant's arguments filed 15 May 2006 regarding claims 2-3 rejected under 35 USC §112 1st paragraph have been fully considered but they are not persuasive.
5. The indicated allowability of claims 13-15 & 19 is withdrawn in view of the newly discovered reference(s) to Bower et al. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-12, 20-23 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There aren't any examples drawn to the treatment or prevention of a clinical condition for which the pharmaceutically or nutraceutically effective compositions are indicated and there is not seen sufficient correlative data to substantiate the preventive efficacy of any of the pharmaceutically or nutraceutically effective compositions set forth in the instant disclosure.

8. Claims 2-3 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diabetic peripheral neuropathy, does not reasonably provide enablement for all peripheral neuropathies or vascular diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Peripheral neuropathies or vascular diseases can be caused by various reasons such as hereditary disorders, systemic or metabolic disorders, infectious or inflammatory conditions, and

exposure to toxic compounds, drugs or miscellaneous causes. Applicant's disclosure does not provide enablement for all of the cause for these two diseases.

Applicants argue the claims are drawn to the preparation of pharmaceutically or nutraceutically effective compositions therefore the specification is not required to produce examples directed to the treatment or prevention of a clinical condition using the compositions. It is recited in the specification specifically pages 1-7 that these compounds are novel in the use of therapeutic, cosmetic and nutraceutical field of alcohols, acids and esters of those acids having long mono- or poly-unsaturated hydrocarbon chain. Based on this disclosure, one would need to enable the treatment or prevention of the clinical conditions recited using the instant compounds contained in the instant compositions.

The following rejection is deemed proper.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 9-16 & 19 rejected under 35 U.S.C. 102(b) as being anticipated by Bower et al. (US Pat. 4,950,688).

US'688 teaches in the instant invention wherein the saturated hydrocarbon chain is not branched and collectively contain from 23 to 35 carbon atoms. See col. 3, lines 36-69; col. 4, lines 1-14 and col. 13, line 48.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 9-12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83

USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation total of from 23 to 35 carbon atoms, and the claim also recites preferably from 25 to 31 carbon atoms which is the narrower statement of the range/limitation.

14. Claim 9 recites the limitation "optionally branched" in line 6. There is insufficient antecedent basis for this limitation in the claim.

As currently written, claim 1 recited that the hydrocarbon chain must be branched. Therefore claim 9 lacks antecedent basis for this limitation.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access

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to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Deborah D. Carr", with a stylized flourish at the end.

DEBORAH D. CARR
PRIMARY EXAMINER

ddc